K120264

APR 11 2012

510(K) SUMMARY

11.1 SUBMITTER INFORMATION

A.	Company Name:	Konan Medical, Inc.
B.	Company Address:	10-29, Miyanishicho, Nishinomiya Hyogo 662-0976, Japan
C.	Company Phone:	+81-798-36-3456
D.	Company Facsimile:	+81-798-26-1028
E.	Contact Person:	Tatsuya Kasahara
F.	Date Summary Prepared:	January 24, 2012

11.2 DEVICE IDENTIFICATION

A.	Device Trade Name:	Konan Specular Microscope XIV, Cellchek Plus
B.	Common Name:	Specular Microscope
C.	Classification Name(s):	AC-powered Slit Lamp Biomicroscope
D.	Classification Regulation(s):	886.1850
E.	Device Class:	Class 2
F.	Product Codes:	NQE
G.	Advisory Panel:	Ophthalmic

11.3 IDENTIFICATION OF PREDICATE DEVICE

The predicate device is the Konan Medical, Inc. Noncon Robo Pachy F&A non-contact specular microscope, which was cleared by FDA under 510(k) number K062763 on February 22, 2008.

11.4 DEVICE DESCRIPTION

The Konan Specular Microscope XIV, CellChek Plus, is a non-contact ophthalmic microscope, optical pachymeter, and camera intended for examination of the corneal endothelium and for measurement of the thickness of the cornea. Cell counting and analysis programs are included, and allow for analysis of the images of the cell distribution of the eye (the same analysis software present in the predicate device is also present in the modified device).

When photographing the corneal endothelium, the equipment performs the alignment and automatically focuses by capturing the reflected light from the patient's eye with the CCD camera. The device permits visual inspection and photography of the corneal endothelium and measurement of the corneal thickness without any object contacting the eye. It features focusing by means of infrared techniques, and computer-assisted cell counting and cell analysis capabilities. The computer functions are also used to aid in setting up the various features of the machine and to aid in photography. Photographic images are temporarily stored in the system's memory, and are preserved by using a printer.

Both the image of the corneal endothelium and the various computerized control functions are displayed on the touch screen.

The parts of the device that come into contact with a patient are the forehead rest and the chin rest. The head rest is comprised of Polytetrafluoroethylene (PTFE), which is known as Teflon®, and the material that comprises the chin rest is Acrylonitrile butadiene styrene (ABS).

11.5 INDICATIONS FOR USE

The Konan Specular Microscope XIV, Cellchek Plus, is a non-contact ophthalmic microscope, optical pachymeter, and camera intended for examination of the corneal endothelium and for measurement of the thickness of the cornea.

11.6 TECHNOLOGICAL CHARACTERISTICS

The Konan Specular Microscope XIV, Cellchek Plus is technically equivalent to the Konan Noncon Robo Pachy F&A non-contact specular microscope. The principal design modification for the device is that the mechanical unit used for alignment has been changed. The modified mechanical unit now consists of five axes (the predicate device had 3 axes) and the optical unit can be placed in any position over the cornea to obtain an image of endothelial cells. A smaller computer mother board was implemented, and a new computer program was installed for the modified mechanical system. The system now operates by means of a touch screen.

11.7 SUMMARY OF TESTING

A. Non Clinical Tests

The following testing was performed on the Konan Specular Microscope XIV, Cellchek Plus:

- The modified CELLCHEK PLUS device was subjected to electrical safety testing in accordance with IEC 60601-1.

- The modified CELLCHEK PLUS device was subjected to electromagnetic compatibility (EMC) testing in accordance with IEC 60601-1-2.
- The modified CELLCHEK PLUS device was subjected to performance testing, including optical radiation safety testing in accordance with ISO 15004-1 and 15004-2.
- The modified CELLCHEK PLUS device was subjected to software validation testing in accordance with IEC 60601-1-4.

B. Clinical Tests

A Clinical test was performed with four "classifiers", each analyzing the same 40 images of eyes by using the Konan predicate device Noncon Robo Pachy F&A non-contact specular microscope. Each classifier analyzed each image three times. The analyses of the classifiers were analyzed for cell density, hexagonality, and coefficient of variation.

Agreement and variability of the analysis methods was obtained using a sample that included virtually no eyes with Percent Hexagonality <45, Coefficient of Variation >0.41, or Cell Density <2100. Agreement and variability of the analysis methods is not known for eyes with parameters beyond these values.

Agreement Between Methods of Analysis

For a single image from each eye, cell density, coefficient of variation and percent hexagonality were determined by each analysis method. For a given parameter and pair of methods of image analysis, agreement between outputs was assessed. This was done by taking the difference between the two outputs for each image and then calculating the mean difference, and the 95% limits of agreement. These measures of agreement between analysis methods were calculated for each parameter. Note that each measure estimates the degree of agreement between the different methods of analysis applied to a single image. It does not take into account variation due to repeated image capture. Variations between different images of the same eye will significantly reduce agreement. The listed values should not be taken as estimates of the agreement of the measurements associated with repeated image capture.

Agreement Between Methods of Analysis for Cell Density			
Analysis Methods	Mean Difference[1] (%) Note : a negative number indicates that first method gives lower results than the second	Limits of Agreement[2] (%) : ~95% of Differences should fall between these figures	
		Lower 95%Limit of Agreement (Mean Difference – 2*sd)	Upper 95%Limit of Agreement (Mean Difference – 2*sd)
Manual vs. PC-Assist (with redrawing)	0.06	-0.78	0.9
Manual vs. PC-Assist (without redrawing)	0.00	-2.3	2.3
Center vs. PC-Assist (with redrawing)	-0.11	-1.47	1.25
Center vs. PC-Assist (without redrawing)	-0.17	2.71	2.37
Manual vs. Center	0.16	-1.1	1.42

Agreement Between Methods of Analysis for Coefficient of Variation			
Analysis Methods	Mean Difference[1] (%) Note : a negative number indicates that first method gives lower results than the second	Limits of Agreement[2] (%) : ~95% of Differences should fall between these figures	
		Lower 95%Limit of Agreement (Mean Difference – 2*sd)	Upper 95%Limit of Agreement (Mean Difference – 2*sd)
Manual vs. PC-Assist (with redrawing)	0.43	-2.35	3.21
Manual vs. PC-Assist (without redrawing)	0.24	-5.62	6.10
Center vs. PC-Assist (with redrawing)	2.38	-4.18	8.94
Center vs. PC-Assist (without redrawing)	2.18	-4.18	8.94
Manual vs. Center	-1.96	-8.58	4.66

Agreement Between Methods of Analysis for Percent Hexagonality			
Analysis Methods	Mean Difference[1] (%) Note : a negative number indicates that first method gives lower results than the second	Limits of Agreement[2] (%) : ~95% of Differences should fall between these figures	
		Lower 95%Limit of Agreement (Mean Difference – 2*sd)	Upper 95%Limit of Agreement (Mean Difference – 2*sd)
Manual vs. PC-Assist (with redrawing)	-0.08	-3.32	3.16
Manual vs. PC-Assist (without redrawing)	1.47	-3.63	6.57
Center vs. PC-Assist (with redrawing)	2.13	-3.03	7.29
Center vs. PC-Assist (without redrawing)	3.67	-3.13	10.47
Manual vs. Center	-2.23	-7.03	2.57

Footnotes:

1. Mean Difference is the average across images of:

$$100 \times \frac{Cell\ Density\ Method1 - Cell\ Density\ Method2}{Cell\ Density\ Method1 + Cell\ Density\ Method2}$$

2. Approximately 2.5% of differences would be expected to fall below the Lower limit of Agreement and about 2.5% would be expected to fall above the Upper Limit of Agreement. The Limits of Agreement are defined as:

   The Mean Difference (footnote 1, above) ±2(standard deviation). The standard deviation is calculated across all of the 40 Differences as defined in footnote 1, above.

Agreement Between Methods of Analysis			
	Correlation Coefficients		
Manual vs. PC-Assist (with redrawing)	R^2=0.8719	R^2=0.2709	R^2=0.0006
Manual vs. PC-Assist (without redrawing)	R^2=0.9813	R^2=0.8185	R^2=0.6659
Manual vs. Center	R^2=0.9636	R^2=0.2041	R^2=0.4307
Center vs. PC-Assist (with redrawing)	R^2=0.8544	R^2=0.201	R^2=0.1846
Center vs. PC-Assist (without redrawing)	R^2=0.955	R^2=0.2318	R^2=0.3811

Chart gives the coefficients of correlation of the parameters indicated at the top of the column when the parameters are computed according to the method indicated in the first column. These tables indicate that cell density has a good correlation with the Manual Method (an exact method); the other parameters are only weakly-correlated, especially without redrawing.

Variability Associated with the Analysis Methods

The variability of the results associated with each analysis method was assessed. For each of the forty images, cell density, coefficient of variation and percent hexagonality were determined by each method. Each analysis was repeated on the same image three times (presentation was randomized) by each of four "classifiers." For a given analysis method, the standard deviation of the within-image results was calculated as a measure of variability.

Note that this measure estimates the variability associated only with repeated application of the analysis method to a single image. Differences between two or more images of the same eye will significantly increase variability. The listed values should not be taken as estimates of the variability of the measurements associated with repeated image capture.

Variability Associated with Analysis Method			
	Standard Deviation (within-image) Expressed as a percentage of the mean value*		
Analysis Methods	Cell Density	Coefficient of Variation	Percent Hexagonality
PC-Assist (with redrawing)	1.14	4.23	3.87
PC-Assist (without redrawing)	0.78	8.02	12.67
Center	1.23	6.60	6.42

*Value in table is the mean across 40 images of the variability standard deviation (square root of the sum of the "within-observer" variance plus the "between-observer" variance) divided by the mean value for the image (expressed as a percentage).

11.8 CONCLUSIONS DRAWN FROM STUDIES

The conclusions drawn from the non-clinical and clinical testing demonstrate that the modified device, Konan Specular Microscope XIV, Cellchek Plus, is substantially equivalent to the Konan predicate device Noncon Robo Pachy F&A non-contact specular microscope.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Konan Medical, Inc.
c/o Mr. David S. Fernquist
2976 Calle Gaucho
San Clemente, CA 92673

APR 11 2012

Re: K120264
Trade/Device Name: Konan Specular Microscope XIV, Cellchek Plus
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered Slit Lamp Biomicroscope
Regulatory Class: II
Product Code: NQE
Dated: March 8, 2012
Received: March 12, 2012

Dear Mr. Fernquist:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Konan Specular Microscope XIV, Cellchek Plus

Indications for Use:

The Konan Specular Microscope XIV, Cellchek Plus, is a non-contact ophthalmic microscope, optical pachymeter, and camera intended for examination of the corneal endothelium and for measurement of the thickness of the cornea.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K120264